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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232
21186	7590	09/10/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,376

Applicant(s)

BODNER, JEFFREY P.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/8/04 (Response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 17.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Response

1. The Applicant's arguments filed 4/8/04 have been fully considered and are convincing, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claim 24, 26, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Comte (US 4640983). Comte teaches a conductor device connecting a cardiac electrode and an electrical pulse generator. The conductor device comprises multi-filar conductors (75, 85) wound coaxially and non-co-radially, the conductors are individually insulated or not, the conductor coils are separated by a sheathing/ tube of material (87), and the conductor are covered with an outer sheathing (77) (abstract; figure 8; col. 3 @ 59 – col. 4 @ 1; col. 9 @ 52–68; col. 10 @ 48-56; col. 10 @ 65 – col. 11 @ 6).

Claim Rejections - 35 USC § 103

3. Claim 1-9, 11-14, 18-20, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201). Comte discloses the claimed invention except for an extendable/ retractable electrode (claims 1, 11, 18, 25) and a means of facilitating rotation of the second conductor (claims 8, 14).

Helland et al. teach an electrode configuration using an electrode assembly with an extendable/ retractable electrode (144) coupled to the second conductor, the electrode rotated by

the means for facilitating rotation/ conductive plug (176) for the purpose of fixing/ securing the electrode to the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an extendable/ retractable electrode coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug in the Conte system in order to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient (figure 6; col. 1 @ 6-11 and 48-58; col. 1 @ 62 – col. 2 @ 5; col. 4 @ 56 – col. 5 @ 15).

4. Claims 10 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201) and further in view of Doan (US 5425755) and further in view of Altman et al. (US 5845396).

As discussed in paragraphs 2 and 3 of this action, modified Comte discloses the claimed invention except the insulative coating being ETFE.

Doan teaches the lead insulation using a biocompatible TEFLON™ coating, such as ETFE, for the purpose of minimizing the frictional resistance between the coated coil and the surrounding insulation. ETFE is a material well known in the conductor art for use as a conductor insulator (US 5845396 to Altman et al. – col. 7 @ 11-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an insulative coating of ETFE in the modified Conte system in order to reduce the coefficient of friction between the outer coil and outer insulation so the lead has increased flexibility facilitating the positioning and fixation in the heart, and so the torque associated with the inner coil and tubing is

reduced when the helix electrode is extended or retracted to minimize damage to the lead
(abstract; col. 2 @ 17-26; col. 4 @ 5-10).

5. Claim 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Helland et al. (US 5545201) and further in view of Altman et al. (US5845396). As discussed in paragraphs 2 and 3 of this action, modified Comte disclose the claimed invention except for the insulation being a polyimide material (claim 21), and the insulation being heat-shrunk PTFE / ETFE material (claims 23).

As to claim 21, Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

As to claims 23, Altman et al. teach a lead with heat-shrunk PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunk PTFE/ ETFE insulated conductors in the modified Comte et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Comte (US 4640983) in view of Altman et al. (US5845396). As discussed in paragraphs 2 of this action, Comte disclose the claimed invention except for the insulation being heat-shrunk PTFE / ETFE material.

Altman et al. teach a lead with heat-shrunk PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunk PTFE/ ETFE insulated conductors in the Comte system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the

Application/Control Number: 09/870,376

Page 6


Art Unit: 3762

organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

fpo
9/1/04


JEFFREY R. JASTRZAB
PRIMARY EXAMINER
3762
9/3/4